



Package leaflet: Information for the patient

LINCOCIN® 500 mg hard capsules **LINCOCIN® Syrup 250 mg/5 ml** Lincomycin

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What LINCOCIN® is and what it is used for
2. What you need to know before you take LINCOCIN®
3. How to use LINCOCIN®
4. Possible side effects
5. How to store LINCOCIN®
6. Contents of the pack and other information

1. What LINCOCIN® is and what it is used for

What LINCOCIN® is

LINCOCIN® contains the active substance lincomycin hydrochloride which belongs to a group of medicines called "systemic antibiotics- lincosamides".

How LINCOCIN® works

This medicine is indicated for the treatment of severe infections caused by certain types of bacteria (staphylococci, pneumococci, streptococci) that cannot be treated with other antibiotics. In particular, LINCOCIN® must be reserved for people who are allergic to penicillin or in cases where the doctor believes that penicillin cannot be used.

Before starting treatment with LINCOCIN®, the physician should carefully consider the possibility of using other, less toxic medicines in order to avoid serious inflammation of the intestine (colitis), depending on the nature of the infection (see section 4. Possible side effects).

During treatment, laboratory tests (to test sensitivity to the medicine) should be performed, as LINCOCIN® may lose effectiveness.

If necessary, this medicine may be taken with other antibiotics.



What LINCOCIN® is used for

LINCOCIN® is used to down or block the growth of bacteria.

2. What you need to know before you take LINCOCIN®

Do not take LINCOCIN® if

- you are allergic to lincomycin hydrochloride or to other similar products (clindamycin) or to any of the other ingredients in this medicine (listed in section 6);
- you suffer from a non-serious infection or an infection caused by a virus (viral infections).

If you develop very severe skin reactions, talk to your doctor immediately.

The use of this medication is not recommended if you:

- you develop **diarrhoea during** treatment with LINCOCIN®, as it can lead to bowel inflammation (colitis), even fatal (see section 4 “Possible Side Effects”). Like other antibiotics, Lincocin can also alter the normal flora of the intestine and it could result in the excessive growth of a bacteria called *Clostridium difficile* that causes diarrhoea. In less serious cases, symptoms resolve after discontinuation of treatment with Lincocin. Your doctor will determine the most appropriate treatment depending on the severity of symptoms, and you will undergo regular check-ups, since *Clostridium difficile*-induced diarrhoea can occur even 2 months after you have discontinued the use of this medicine;
- you suffer from **stomach or intestinal disorders**;
- you have a hereditary predisposition to develop **severe allergic reactions** (anaphylactic reactions);
- you have **liver disorders**, unless clearly necessary;
- you suffer from **problems with your kidneys**;
- you are undergoing treatment with **erythromycin**, another antibiotic used for the treatment of infections caused by bacteria (see section “Other Medicines and Lincocin”);
- you suffer from an infection in the membrane that lines the brain, called **meningitis**, as Lincocin is not effective in such case.

Tell your doctor if any of the following conditions applies to you:

- you are undergoing treatment with other **medicines that provide muscle relaxation** (medicines with neuromuscular blocking properties), because, in this case, Lincocin must be administered with caution (See section “Other Medicines and Lincocin”);
- you’ve had **asthma** or other allergic reactions in the past;
- you are undergoing treatment with medicines that reduce the natural intestinal movements (**antiperistaltic drugs**) such as opiates and diphenoxylate with atropine, as they could worsen the possible side effects of Lincocin on the intestine;
- if you are **debilitated**, as you have a higher risk of possible side effects on the intestine with this medication;
- if you are **elderly** (see section “Elderly”).

During treatment, this medicine can lose efficacy and lead to the development of more serious infections (superinfections). In this case, your doctor will prescribe the appropriate treatment.



If you suffer from an infection caused by a fungus (moniliasis), your doctor will also prescribe, concurrently with Lincocin, a medicine that specifically targets moniliasis infections (anti-monilial treatment).

Laboratory tests

During long-term treatment with LINCOCIN[®], your doctor will perform regular blood tests and controls of liver and kidney function.

Elderly

If you are elderly, during treatment with LINCOCIN[®], the doctor will carry out periodic check-ups since you have a higher risk of possible side effects on the intestine with this medication, such as diarrhoea.

Other medicines and LINCOCIN[®]

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Tell your doctor if you're taking the following medicines:

- **neuromuscular blocking agents** (medicines used to provide muscle relaxation, especially before surgical procedures);
- **erythromycin** and **clindamycin** (antibiotics used to treat infections caused by bacteria).

Pregnancy and breast-feeding

If you are pregnant, think you may be pregnant or are planning to have a baby, or if you are breast-feeding, ask your doctor or pharmacist for advice before taking this medicine.

Do not take LINCOCIN[®] if you're pregnant or breast-feeding.

Driving and using machines

There is no data available to determine the effects of this medicine on the ability to drive or use machines.

LINCOCIN[®] contains lactose

This medicinal product contains lactose, a type of sugar. If your doctor has diagnosed you with an intolerance to certain sugars, notify your doctor before taking this medicine.

3. How to use LINCOCIN[®]

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

- Serious infections: one 500 mg capsule every 8 hours;
- Very serious infections: one 500 mg capsule every 6 hours.

We recommend not ingesting anything, except water for 1 to 2 hours both **before** and **after** taking LINCOCIN[®].

Use in individuals with serious kidney problems

If you suffer from serious kidney problems (seriously compromised kidney functionality), your doctor will prescribe doses of this medication that are lower than the recommended dosage.



If you use more LINCOCIN[®] than you should

There are no known cases of overdosage.

If you take more LINCOCIN[®] than you should, discontinue treatment and talk to your doctor immediately or go to the nearest hospital.

If you forget to use LINCOCIN[®]

If you forgot to take a dose, take a dose as soon as you remember. Do not take a double dose to make up for a forgotten dose. If you think you missed more than one dose, talk to your doctor.

If you have any questions about how to use this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

You may experience the following side effects:

Common (may affect up to 1 in 10 people):

- diarrhoea, nausea, vomiting

Uncommon (may affect up to 1 in 100 people):

- infection of the vagina
- skin rash, hives

Rare (may affect up to 1 in 1,000 people):

- itching

Unknown frequency (Frequency cannot be estimated from the available data):

- persistent diarrhoea that may be a symptom of serious bowel inflammation (see section “Warnings and Precautions”);
- reduction in white blood cell count (neutropenia, leukopenia, agranulocytosis), formation of red-brown spots in the skin, caused by a decrease in blood platelet count (thrombocytopenic purpura), reduction in red blood cell count (aplastic anaemia) or reduction of all types of blood cells (pancytopenia);
- allergic reactions, such as swelling of the face, lips and tongue (angioedema), very serious allergic reactions (serum sickness and anaphylactic reactions);
- inflammation of the oesophagus (oesophagitis), abdominal discomfort;
- yellowing of the skin, mucous membranes and of the eyes, caused by liver problems and changes in the results of some liver function tests;
- very serious skin reactions:
 - sudden appearance of severe skin rash or blistering and peeling of the skin, possibly accompanied by high fever or joint pain (toxic epidermal necrolysis (TEN))
 - skin rash characterised by the rapid appearance of areas of red skin studded with small pustules (small blisters filled with white/yellow fluid) (Acute Generalised Exanthematous Pustulosis (AGEP))
 - widespread skin rash with blistering and peeling of large areas of skin, particularly around the mouth, nose, eyes or genitals (Stevens Johnson syndrome (SJS))



- skin rash, which may blister, and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge (erythema multiforme);
- irritation and inflammation of the skin (exfoliative dermatitis, bullous dermatitis).

Other side effects:

- inflammation of the tongue (glossitis) or of the oral mucosa (stomatitis), bowel inflammation (enterocolitis), itching near the anus (anal),
- kidney disorders (renal dysfunction) characterised by increases in blood nitrogen levels (azotaemia), decreased urine output (oliguria) and/or the presence of proteins in the urine (proteinuria);
- dizziness and perception of buzzing inside the ear (tinnitus).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system and include batch/Lot number if available. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store LINCOCIN®

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the package and on the ampoule/vial after "EXP". The expiry date refers to the last day of that month.

Store at controlled room temperature 15°C-30°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What LINCOCIN® contains

The active substance is lincomycin (e.g. lincomycin hydrochloride).

Each capsule contains 544.81 mg of lincomycin hydrochloride (equivalent to 500 mg lincomycin base).

Each syrup contains 272.40 mg of lincomycin hydrochloride (equivalent to 250 mg lincomycin base).

The other ingredients are: talc, magnesium stearate, **lactose monohydrate**.

The hard capsule is composed of gelatine, titanium dioxide, indigo carmine aluminium lake, iron oxides.

What LINCOCIN® looks like and contents of the pack

The 500 mg LINCOCIN® hard capsules are available in a PVC/aluminium blister pack containing 12 capsules.

LINCOCIN® Syrup 250 mg/5 mL is available in 60 mL bottle.

Lincocin Oral/PIL/PK-01

According to Italy approved SPC dated: 19 May 2022 & approved information in Pakistan



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Pfizer Pakistan Limited